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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,314	05/17/2005	David Wallach	WALLACH33	6672
1444 7590 01/05/2010 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303				
EXAMINER				
SWOPE, SHERIDAN				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
01/05/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/511,314

**Applicant(s)**

WALLACH ET AL.

**Examiner**

SHERIDAN SWOPE

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October and 23 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20, 25, 69, 70, 72, 82-91, 100, 102 and 104 is/are pending in the application.
- 4a) Of the above claim(s) 20, 25, 72, 84, 89, and 100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69, 70, 82, 83, 85-88, 90, 91, 102, and 104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' filings of October 16 and November 23, 2009, in response to the action mailed April 20, 2009, are acknowledged. It is acknowledged that applicants have cancelled Claims 75, 103, and 105 and amended Claims 69, 70, 82, 83, 87, 88, 102, and 104. Claims 20, 25, 69, 70, 72, 82-91, 100, 102, and 104 are pending. The elected invention is directed to a method for treatment of rheumatoid arthritis, a disease involving IL-2, using the NIK polypeptide of SEQ ID NO: 18. Claims 20, 25, 72, 84, and 89 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b). It is noted that Claim 100 is dependent from the cancelled claim, Claim 98, while Claim 98 was originally dependent from independent Claim 76, which is also cancelled. Claim 100 no longer depends from an independent claim and the recited subject matter is unclear. Therefore, Claim 100 is herein withdrawn, as not being encompassed by the elected invention. Claims 69, 70, 82, 83, 85-88, 90, 91, 102, and 104 are hereby reconsidered.

#### ***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### **Enablement**

Rejection of Claims 69, 70, 82, 83, 85-88, 90, 91, 102, 104, and 105 under 35 U.S.C. 112, first paragraph/lack of enablement, for the reasons explained in the prior actions, is maintained.

It is noted that no new arguments were presented in the filing of October 16, 2009.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments in their response of November 23, 2009. (A) In the interview [of October

23, 2009], it was suggested that claim 69 be amended along the lines of "A method of modulating cytokine stimulating cyc signaling, comprising administering to a subject in need thereof an amount of a polypeptide effective to bind to cyc and inhibit the interaction between cyc and NF- $\kappa$ B inducing kinase (NIK). (B) As to the enablement rejection, with respect to the peptide itself, the examiner suggested revising claims 69 and 70 in the manner done herein.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: Applicants have mis-represented the content of the interview of October 23, 2009. The claims, as amended, encompass "A method of modulating cytokine stimulating cyc signaling, comprising administering to a subject in need thereof...". Thus, the claims continue to be directed to a method of treatment. The Examiner never suggested that the peptide of SEQ ID NO: 18 has use in the treatment of any disease or disorder. As clearly stated in the prior actions, the specification fails to provide evidence that any disease can be treated with the peptide of SEQ ID NO: 18: see the actions of April 11, 2007 (pg 7), January 3, 2008 (pg 4-5), September 25, 2008 (pg 6-7), and April 20, 2009 (pg 4-5).

It was acknowledged in the prior actions that the specification provides evidence that the peptide of SEQ ID NO: 18 inhibits NIK-induced activation of NF- $\kappa$ B transcription in cultured cells (pg 20, para 3). However, said evidence is not sufficient such that the skilled artisan would believe that, more likely than not, the peptide of SEQ ID NO: 18 is useful in the treatment of any disease.

(B) Reply: It is acknowledged that, with respect to the peptide of SEQ ID NO: 18, the claims have been amended to recite the functional limitation of "the ability thereof to bind to

cyc and inhibit cyc/NIK interaction". However, said limitation does not enable the skilled artisan to treat any disease or disorder.

For these reasons and those explained in the prior actions, rejection of Claims 69, 70, 82, 83, 85-88, 90, 91, 102, 104, and 105 under 35 U.S.C. 112, first paragraph/lack of enablement, is maintained.

### **Written Description**

Rejection of Claims 69, 70, 82, 83, 85-88, 90, 91, 102, 104, and 105 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior actions, is maintained.

It is noted that no new arguments were presented in the filing of October 16, 2009.

In support of their request that said rejection be withdrawn, Applicants provide the following comment in their response of November 23, 2009. As to the written description rejection, with respect to the peptide itself, the examiner suggested revising claims 69 and 70 in the manner done herein.

Said argument is not found to be persuasive for the following reason. It is acknowledged that, with respect to the peptide of SEQ ID NO: 18, the claims have been amended to recite the functional limitation of "the ability thereof to bind to cyc and inhibit cyc/NIK interaction". However, said limitation does not describe the treatment of any disease or disorder such that the skilled artisan would recognize possession.

### ***Allowable Subject Matter***

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment

or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

#### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652